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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,362	03/12/1999	DENIS MARIE BERNARD CHENEBAUX	P63163USO	1607

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	20

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/147,362	CHENEBAUX, D. M. B., ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/30/01 & 05/07/02* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the communications filed 30 July, 2001, and 07 May, 2002. Claims 15-30 were canceled without prejudice or disclaimer and new claims 31-43 introduced. Claims 31-43 are currently under examination.

35 U.S.C. § 112, Second Paragraph

2. Claims 40 and 41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rewritten claims are still vague and ambiguous. For instance, the method cites the use of a peptide that was "previously detectably labeled". The actual structure and properties of the peptide are not readily manifest. Is the peptide still labeled or has the label since been removed? Moreover, the methodology steps are still deficient and fail to allow the skilled artisan to carry out the claimed invention without any additional guidance. Appropriate correction is required (i.e., An immunoassay method for the detection of HIV-1 type O-specific antibodies comprising the following steps: 1) obtaining a patient sample suspected of containing HIV-1-specific antibodies; 2) contacting said sample with an antigen comprising an immobilized peptide according to claim 15 under conditions that permit the formation of an antigen-antibody complex; 3) removing any non-specifically bound antibody through repeated washes; 4) detecting the formation of said antigen-antibody complex by admixing a labeled antibody specific for patient antibodies; etc.).

3. Claims 42 and 43 are vague and indefinite for failing to clearly set forth the salient characteristics of the kit. For instance, a

diagnostic kit often comprises vials or containers containing the peptide of interest, suitable reagents for performing the reaction of interest (e.g., buffers and assay reagents), and directions to perform the assay of interest. However, the simple recitation of a kit simply comprising a peptide is insufficient. Is the peptide in any type of container? Are there any additional reagents present to perform a diagnostic assay? Appropriate correction is required (i.e., A diagnostic kit for the detection of HIV-1 type O-specific antibodies comprising the following: 1) a container comprising a synthetic peptide according to claim 1; 2) a container comprising a labeled antibody for the detection of peptide-antibody complexes; 3) a container comprising a buffer to remove unbound antibody; etc.).

35 U.S.C. § 112, First Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 31-43 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rewritten claims are still broadly directed toward synthetic peptides comprising the core motif Trp-Gly-Cys-Φ-Cys-Tyr-Thr-Ser varying in length between 13-33 and 26-66 amino acids depending upon the oligomeric form of the peptide (i.e., monomeric or dimeric). The claims still potentially encompass a large genus of peptides. However, the

specification only provides a small number of peptides (e.g., see claim 35) with minor variations in amino acid sequence. Appropriately drafted claim language directed toward these embodiments would be acceptable (i.e., An isolated and purified synthetic peptide selected from the group of peptides having SEQ ID NO.: 1, SEQ ID NO.: 2, SEQ ID NO.: 3, etc.). However, the disclosure does not support the exceedingly large breadth of the claims.

The legal considerations that govern enablement determinations pertaining to undue experimentation are disclosed in *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988) and *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows: 1) The prior art is unpredictable and teaches that single amino acid changes, as well as, the addition or deletion of flanking regions, in any given peptide can abrogate antigen-antibody binding interactions (Alexander *et al.*, 1992; Schoofs *et al.*, 1988). For instance, Alexander and colleagues noted that "protein antigenicity can be significantly reduced by alteration of single critical residues." Such substitutions probably induce local changes in the epitope that lead to steric collisions thereby hindering antibody recognition and binding. The disclosure fails to provide adequate guidance pertaining to those substitutions that are permissible and retain the antigenicity of the peptide.

2) The disclosure fails to provide adequate guidance pertaining to the molecular determinants modulating the antigenic characteristics of the claimed peptides. In order to make the various substitutions encompassed by the claims, the skilled artisan would require a knowledge of the epitopic molecular determinants. In the absence of sufficient guidance pertaining to this issue, undue experimentation would be required to ascertain all the various substitutions that would be permitted.

3) The disclosure only provides a small number of working embodiments involving a small number of closely related peptides. The disclosure fails to provide any additional working embodiments or sufficient guidance pertaining to acceptable substitutions.

4) The claims are of excessive breadth and encompass an exceedingly large genus which is inadequately supported by the disclosure. The claims encompass a large genus of compounds, however, as noted *supra*, the disclosure fails to provide sufficient guidance pertaining to the identification of critical molecular determinants and acceptable amino acid substitutions. The unpredictability of the prior art provides another hurdle for the skilled artisan to overcome.

Applicants' argument have been carefully considered but are not deemed to be persuasive for the reasons of record set forth *supra*. Accordingly, when all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation to practice the claimed invention in a manner commensurate in scope with the claims.

Finality of Office Action

6. Applicants' amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). **A SHORTENED STATUTORY PERIOD**

FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

7. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

8. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

05 September, 2002

JAMES HOUSEL 9/9/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600